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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,539	04/05/2001	Howard Preissman	PX-02-2	9912

21394 7590 01/11/2007

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	PAPER NUMBER
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/828,539	PREISSMAN, HOWARD	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-44,46-56,58-70,72 and 73* is/are pending in the application.

4a) Of the above claim(s) *33-39 and 46-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-44, 54-56, 58-70, and 72-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 12, 2006 has been entered.

Interview

Applicant requested an interview prior to examination of the present claims and completion of the current response. However, the examiner attempted to call the attorney for applicant several times for the interview but was unable to reach them. Due to time constraints, the examiner needed to go forward with the examination. Applicant's arguments were thoroughly taken into consideration and replied to below. Applicant is invited to contact the examiner upon receipt of this office action to discuss and have a phone interview at that time.

Response to Arguments

Applicant's arguments filed September 12, 2006 have been fully considered but they are not persuasive.

The applicant has argued that Ersek's particles are not inherently individually visible, since the limitation requires a specific concentration to be visible. The examiner disagrees. Not only is a specific concentration not claimed, a preferred concentration is not even disclosed in the specification. If the concentration were a key factor in the visibility of the particles, it would think to be at least disclosed in the specification. The examiners position remains that since

Ersek discloses the same size of particles, they will inherently be visible, since they are of the same size as applicants particles.

Applicant further argues Ersek's particles will not be inherently individually visible since the carrier vehicle is disclosed to be metabolized in the body (thus the particles would be clumped together and not dispersed and individual). Although it may be true that the vehicle might *eventually* metabolized, there is no telling the time period for how long this will take. Further, the applicant has claimed an *injectable composition*, particles visible *during implantation*. Therefore, even if the vehicle were to be metabolized, this would occur *after* delivery, and the vehicle would still be present *during* delivery (which is also when the surgeon would be viewing the particle flow), thus not altering the concentration of the particles during delivery (the time period applicant has claimed). That is, they will remain dispersed in the vehicle (not clumped together with the absence of a vehicle), thus individually visible due to their size during delivery.

The applicant also has argued that Ersek's vehicle is not a matrix as claimed. The examiner disagrees. Matrix, in its ordinary meaning may be defined as a material in which something is enclosed or embedded (Merriam-Webster's Collegiate Dictionary, 10th Edition, 2001). The particles are embedded and enclosed within the vehicle of Ersek. Ersek's vehicle may be considered a matrix. Ersek's possible materials for the vehicle/matrix are seen at col.2, lines 47-52 and seen in figure 4.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

> pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-44, 54-56, 58-61, and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 40, line 4 recites, "size between about 350u and *about* 2200u". Applicant only has support for "size between about 350u and 2200". Claims 41-44, 54-56, 58-61, and 70 depend upon claim 40 and inherit all problems associated with the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 62-69 and 72-73 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 62 recites the limitation "the implant material" in line 6. There is insufficient antecedent basis for this limitation in the claim. Claim 73 recites the same limitation. Claims 63-69 and 72-73 depend upon claim 62 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 44, 54-56, 58-59, 61, 62, 63, 64, 65, 68, 69, 70, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (US 5,258,028, cited previously).

Referring to claim 62, Ersek discloses an injectable composition (see fig.3, 4; col.2, lines 12-21; col.9, lines 21-25) comprising a flowable matrix (physiologic vehicle 31; col.2, lines 47-52) and radiopaque tracer particles (30; disclosed to be radiopaque, col.3, lines 15-19; col.10, lines 22-27) having a size of between about 350 microns and 2200 microns (col.2, lines 35-39), and wherein the particles are individually visible during implantation (inherently Ersek's particles are individually visible, since they are the same size as the applicant's particles, therefore, would have to be just as visible as the applicant's particles).

Referring to claim 64, Ersek discloses the claimed flowable matrix materials, such as polymer based materials (physiologic vehicle, col.2, lines 47-52, starch, hydrogel, polyvinylpyrrolidones and other polymeric materials, etc).

Referring to claim 65, Ersek discloses the radiopaque particles to comprise barium compounds (col.10, lines 22-28).

Referring to claims 68-70, Ersek discloses the radiopaque particles to be sized between about 570u and 2200u, or between about 450u and 1600u and 570 and 1150 (all ranges fall within Ersek's disclosed range of between about 30u and 3000u; col. 2, lines 35-39).

Referring to claim 73, Ersek discloses PMMA as part of the *implant material* (col.6, lines 50-55) and barium sulfate as the particles (col.10, lines 22-28).

Referring to claims 40, 44, 54-56, 58-59, 61, and 63:

It is recognized by the examiner that a board decision was made for claims 40-44 (see board decision August 10, 2005), similar subject matter which is claimed in claim 63, and the other claims listed are from which they depend, the decision which reversed the examiner on a 102 rejection over Ersek (US 5,258,028). *The reverse was cited to be improper not because of the size assessment, but instead the rationale cited, relating to obviousness instead of anticipation "if* Ersek were *to choose* 350um..". However, it is noted that this reference is now being applied to the claims in a different light/perspective and rationale, thus is considered a new rejection, relying on anticipation and not obviousness, see below.

Because the current rejection of the above claims is related to the board decision made on August 10, 2005, the examiner would like to respond on one comment made in the decision. The board cited col.3, lines 45-49 to indicate the need of Ersek to have a uniform particle size. However this is not what is recited at all. Ersek recites, "While in *most situations* the particles are of *random size* and configuration, but within the constraints of the size indicated, it is generally desirable that the particles be of generally uniform *configuration*". That is, Ersek disclosed uniform *configuration*, not size. Further Ersek discloses a random size is preferred in *most situations*. Ersek further discloses that it is preferred to have a range of varied particle sizes, smaller and larger than the target size (col.5, line 64-col.6 line 2), further emphasizing the need from a varied sized composition.

Ersek discloses an injectable composition (see fig.3, 4; col.2, lines 12-21; col.9, lines 21-25) comprising a flowable matrix.(physiologic vehicle 31; col.2, lines 47-52) and radiopaque tracer particles (30; disclosed to be radiopaque, col.3, lines 15-19; col.10, lines 22-27) wherein the particles are individually visible during implantation (inherently Ersek's particles are

individually visible, since they are the same size as the applicant's particles, therefore, would have to be just as visible as the applicant's particles) and contrast particles that enhance the visibility of the matrix. Ersek discloses a particle range of 30-3000um. The applicant has claimed two different particle ranges, 350u-2200u and 120u-350u, which overlap at 350um. Both claimed particle ranges (along with applicant's overlap size 350um) fall within Ersek's disclosed particle range. Because Ersek's particle range of 30um-3000um includes 350um, 350um is anticipated by Ersek. Further, Ersek discloses that within any target particle size, there will be a percent of larger particles and a percent of smaller particles (see col.5, line 64-col.6, line 2), thus inherently 2 ranges at least are present (larger and smaller as disclosed by Ersek). The above claims are considered by the examiner to be anticipated by Ersek.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

In the alternative to the above rejection, claims 40-44, 54-56, 58-61, 63, 66, 67, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. (US 5,258,028, cited previously). Referring to claims 40 and 63, Ersek discloses an injectable composition (see fig.3, 4; col.2, lines 12-21; col.9, lines 21-25) comprising a flowable matrix (physiologic vehicle 31; col.2, lines 47-52) and radiopaque tracer particles (30; disclosed to be radiopaque, col.3, lines 15-19; col.10, lines 22-27) wherein the particles are individually visible during implantation (inherently Ersek's particles are individually visible, since they are the same size as the

applicant's particles, therefore, would have to be just as visible as the applicant's particles) and contrast particles that enhance the visibility of the matrix. Ersek discloses a particle range of 30-3000um. The applicant has claimed two different particle ranges, 350u-2200u and 120u-350u. Both claimed particle ranges fall within Ersek's disclosed particle range. It is also noted that applicant's two particle ranges overlap at 350u, which also falls within Ersek's disclosed particle range. Although Ersek has disclosed a wide particle range, *including* 350um (applicants particle overlap), and further discloses that in any target particle size, some larger and smaller will be present, col.5, line 64-col.6, line 2, Ersek does not specifically disclose the particle size 350 (which would include both ranges of applicants particles) or two different ranges of particles within Ersek's range to be present. It would have been obvious to one having ordinary skill in the art at the time the invention was made, for Ersek to have a particle size of 350um (especially since this size falls within Ersek's disclosed range of 30-3000um) or two different particle sizes within Ersek's disclosed range (30-3000um), since wherein the general conditions of a claim have been disclosed in the prior art (size range of 30-3000) it is not inventive to discover the optimum or workable ranges by routine experimentation (350um or two sizes or two particles of different sizes within 30-3000um). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Referring to claims 60, 67, and 72, Ersek discloses a composition of a matrix (vehicle) and particles, however is silent to mention the percent weight of the particles within the matrix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the percent weight 1 or 10 percent, since wherein the general conditions of a claim have been disclosed in the prior art (particle concentrated in a matrix) it is not inventive to

discover the optimum or workable ranges by routine experimentation (1 or 10 percent weight particles within matrix). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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